

WHAT IS CLAIMED IS:

1. A method of treating a proliferative disease in a patient in need of such treatment, comprising administering to said patient, a therapeutically effective amount of a combination of (1) a liposomal anthracycline composition in association with (2) a growth factor receptor inhibitor.

2. The method of Claim 1, wherein said growth factor receptor inhibitor is an antibody directed against the extracellular domain of a growth factor receptor, and said patient is a treatment experienced patient having a proliferative disease and/or has at least one cardiac risk factor and/or has had previous anthracycline therapy.

3. The method of Claim 2, further comprising an additional antineoplastic agent.

4. The method of Claim 2, wherein the liposomal anthracycline composition is pegylated liposomal doxorubicin comprising:

a) doxorubicin HCl;
b) N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-*sn*-glycero-3-phosphoethanolamine sodium salt;
c) fully hydrogenated soy phosphatidylcholine;
d) cholesterol;
histidine, hydrochloric acid and/or sodium hydroxide, ammonium sulfate, and sucrose; wherein the weight percentage ratio of a:b:c:d is about 1.0 :1.60 : 4.80 : 1.60 mg/mL respectively.

5. The method of Claim 3 wherein the liposomal anthracycline composition is pegylated liposomal doxorubicin comprising:

a) doxorubicin HCl;
b) N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-*sn*-glycero-3-phosphoethanolamine sodium salt;

5 c) fully hydrogenated soy phosphatidylcholine;
d) cholesterol;
histidine, hydrochloric acid and/or sodium hydroxide, ammonium sulfate, and
sucrose; wherein the weight percentage ratio of a:b:c:d is about 1.0 :1.60 : 4.80 :
1.60 mg/mL respectively.

6. The method of Claim 4 wherein the antibody is a monoclonal antibody
directed against the extracellular domain of an erbB-2 tyrosine kinase receptor
expressed on the surface of human malignant cancer cells.

10 7. The method of claim 6 wherein the monoclonal antibody is
Trastuzumab.

15 8. The method of Claim 6 wherein the pegylated liposomal anthracycline
composition and the antibody directed against the extracellular domain of a growth
factor receptor are administered sequentially.

20 9. The method of Claim 6 wherein the pegylated liposomal anthracycline
composition is administered first.

25 10. The method of Claim 6 wherein the antibody directed against the
extracellular domain of a growth factor receptor is administered first.

11. The method of Claim 3 wherein the antibody is trastuzumab.

25 12. The method of Claim 6 wherein the proliferative disease is breast
cancer, lung cancer, pancreatic cancer, colon cancer, myeloid leukemia,
melanoma, thyroid follicular cancer, bladder carcinoma, glioma, myelodysplastic
syndrome, ovarian cancer or prostate cancer.

30 13. The method of Claim 11 wherein the proliferative disease is breast
cancer, lung cancer, pancreatic cancer, colon cancer, myeloid leukemia,

melanoma, thyroid follicular cancer, bladder carcinoma, glioma, myelodysplastic syndrome, ovarian cancer or prostate cancer.

14. The method of Claim 11 wherein the additional antineoplastic agent is
5 selected from the group consisting of: Uracil mustard, Cyclophosphamide, Ifosfamide, Melphalan, Chlorambucil, Temozolomide, 5-Fluorouracil, Fludarabine phosphate, Gemcitabine, Paclitaxel, Docetaxel, Interferons, Etoposide, Tamoxifen, Leuprolide, Flutamide, Toremifene, Cisplatin, Carboplatin, Navelbene, CPT-11, Anastrazole, Letrazole, and Capecitabine.

10 15 16. The method of Claim 11 wherein (1) the pegylated liposomal anthracycline composition, (2) the antibody directed against the extracellular domain of a growth factor receptor, and (3) the additional antineoplastic agent are administered sequentially.

20 25 17. The method of Claim 15 wherein said proliferative disease is lung cancer, pancreatic cancer, colon cancer, myeloid leukemia, melanoma, glioma, thyroid follicular cancer, bladder carcinoma, myelodysplastic syndrome, breast cancer, ovarian cancer or prostate cancer.

18. The method of Claim 4 wherein the proliferative disease is an epithelial cancer.

30 19. The method of claim 4 wherein the pegylated liposomal anthracycline composition is administered in the amount of about 20 to about 50 mg/m², given over a time period of about 45 to about 90 minutes, every three to four weeks.

20. The method of claim 4 wherein the antibody directed against the extracellular domain of a growth factor receptor is administered first in the amount

of about 2 to about 6 mg/kg given once over a time period of about 60 to about 90 minutes and subsequently administered in the amount of about 2 to about 6 mg/kg given over a time period of about 60 to 90 minutes every one to four weeks.

5 21. The method of claim 5 wherein the additional antineoplastic agent is administered in the amount of about 400 to about 600 mg/m² given over a time period of about 20 to about 60 minutes every two to four weeks.

10 22. The method of claim 5 wherein the antibody is Trastuzumab.

15 23. The method of claim 5 wherein the additional antineoplastic agent is cyclophosphamide.

20 24. The method of claim 11 wherein

15 a) the pegylated liposomal doxorubicin composition is administered in the amount of about 20 to about 50 mg/m² given over a time period of about 45 to about 90 minutes every three to four weeks.

20 b) Trastuzumab is administered first in the amount of about 2 to about 8 mg/kg given over a time period of about 60 to about 90 minutes and subsequently administered in the amount of about 2 to about 8 mg/kg given over a time period of about 60 to about 90 minutes every one to four weeks; and

25 c) the additional antineoplastic agent is Cyclophosphamide and is administered in the amount of about 400 to about 600 mg/m² given over a time period of about 20 to about 60 minutes every two to four weeks.

25 25. The method of claim 24 wherein (1) the pegylated liposomal doxorubicin composition is administered first, followed by (2) Cyclophosphamide and then (3) Trastuzumab.